

Name of Document	Date of Issuance ¹	Date of Publication in the FEDERAL REGISTER	FEDERAL REGISTER cite
Guidance to Industry Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review	May 20, 1998	May 21, 1998	63 FR 27988
List of Devices for Third Party Review Under the FDA Modernization Act of 1997 ²	February 8, 1999 (list updated periodically)	N/A	N/A
List of Accredited Persons For 510(k) Review under the FDA Modernization Act of 1997 ²	October 2, 1998 (list updated periodically)	N/A	N/A
Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997	October 30, 1998	November 2, 1998	63 FR 58746
Guidance on Criteria and Approaches for Postmarket Surveillance	November 2, 1998	November 3, 1998	63 FR 59315
Guidance for Industry: General/Specific Intended Use	November 4, 1998	November 5, 1998	63 FR 59793
Guidance on Frequently Asked Questions on the Recognition and Use of Consensus Standards ² (Level 2)	December 21, 1998	N/A	N/A

Notices

Medical Devices; Exemptions From Premarket Notification; Class II Devices		January 21, 1998	63 FR 3142
Medical Devices; Exemptions From Premarket Notification and Reserved Devices; Class I		February 2, 1998	63 FR 5387
Medical Devices; Device Tracking; New Orders to Manufacturers		March 4, 1998	63 FR 10638
Prompt Review of Supplemental Applications for Approved Devices		May 21, 1998	63 FR 27987
Modifications to the List of Recognized Standards; Availability; Withdrawal of Draft Guidance "Use of IEC 60601 Standards; Medical Electrical Equipment"		October 16, 1998	63 FR 55617

Rulemakings

Medical Devices; Reports of Corrections and Removals; Direct Final Rule		August 7, 1998	63 FR 42229
Medical Devices; Reports of Corrections and Removals; Companion to Direct Final Rule; Proposed Rule		August 7, 1998	63 FR 42300
Medical Devices; Exemptions from Premarket Notification ; Class II Devices		November 3, 1998	63 FR 59222
Medical Devices; Exemption from Premarket Notification and Reserved Devices; Class I		November 12, 1998	63 FR 63222
Medical Devices; Investigational Device Exemptions; Final Rule		November 23, 1998	63 FR 64617

¹ The "Date of Issuance" is the date that the guidance was announced on the Internet.

² Not applicable (N/A)—this document was not announced in the FEDERAL REGISTER. It was issued directly on the Internet.

III. Electronic Access

Persons with access to the Internet may obtain the documents using the World Wide Web (WWW). For WWW access, connect to CBER at "http://www.fda.gov/cber/guidelines.htm" for the guidance documents only. Connect to CDRH at "http://www.fda.gov/cdrh" for all of the documents listed.

Dated: April 19, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99-10290 Filed 4-23-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Biologic Specimen-Based Study of Dietary Measurement Error for Nutritional Epidemiology and Surveillance

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 23, 1998 page 34190-34191 and allowed 60 days for public comment. No public

comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

Proposed Collection

Title: Biologic specimen-based study of dietary measurement error for nutritional epidemiology and surveillance. *Type of Information Collection Request:* New. *Need and use of Information Collection:* The agency conducts and funds studies examining the relationship between diet and chronic diseases. The study will collection a sample of 400 free-living men and women, 40-69 years of age, two 24-hour dietary recalls, two food frequency questionnaires, a physical activity questionnaire, a dietary screener questionnaire, and an opinion form. Respondents will receive a dose of doubly labeled water and provide spot urine samples to measure energy expenditure, will collect two 24-hour urines to measure urinary nitrogen, and

provide blood samples to measure biochemical measures of dietary intake. The data will be used to assess the magnitude and structure of dietary

measurement error in dietary surveillance and nutritional epidemiologic studies. *Frequency of response:* One-time study. *Affected*

public: Individuals or households. *Types of Respondents:* US adults 40–69 years of age. The annual reporting burden is as follows:

Data collection	Estimated Number of respondents	Estimated Number of responses per respondent	Average burden hours per response	Estimated total hour burden	Estimated total annual burden hours requested
Screener	400	1	0.167	67	67
24-hour recall #1	400	1	0.5	200	200
24-hour recall #2	400	1	0.5	200	200
Food frequency questionnaire #1	400	1	1	400	400
Food frequency questionnaire	400	1	1	400	400
Physical activity questionnaire	400	1	0.25	100	100
Opinion forms	400	1	0.25	100	100
Dietary screener questionnaire	400	1	0.167	67	67
Dosing with DLW/initial urine collections	400	1	4	1600	1600
Spot urine collections	400	1	0.25	100	100
24 hr urine collection #1	400	1	0.167	67	67
24 hr urine collection #2	400	1	0.167	67	67
Blood collection	400	1	0.25	100	100
Total	400	1	0.67	3,468	3,468

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proposed performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimate public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Amy F. Subar, Ph.D., Project Officer, National

Cancer Institute, EPN 313,6130 Executive Blvd MSC 7344, Bethesda MD 20892–7344, or call non-toll-free number (301) 496–8500, or FAX your request to (301) 435–4710, or E-mail your request, including your address, to amy__subar@nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: April 15, 1999.

Reesa Nichols,

NCI Project Clearance Liaison.

[FR Doc. 99–10372 Filed 4–23–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Sickle Cell Disease Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Sickle Cell Disease Advisory Committee.

Date: June 7, 1999.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: For discussion of program policies and issues.

Place: National Institute of Health, Two Rockledge Center, Suite 9104, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Charles L. Peterson, Director, Blood Diseases Program, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, NIH, Two Rockledge Center, Room 10158, MSC 7950, 6701 Rockledge Drive, Bethesda, MD 20892, 301/435–0050.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research, 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 16, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–10368 Filed 4–23–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the